510(k) Summary

OCT 26 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K072612

Applicant:	Beckman Coulter, Inc. 1000 Lake Hazeltine Drive Chaska, MN 55318
Contact person:	Rachelle Parsons, RAC Sr. Regulatory Affairs Specialist Phone: 952.368.1227 Fax: 952.368.7610
Date prepared:	August 21, 2007
Proprietary name:	Access® BR Monitor and Access BR Monitor Calibrators on the Access Immunoassay Systems
Common name:	Immunoassay for the determination of CA 15-3 antigen
Product classification:	Class II
Product code:	MOI, JIT
Predicate device:	Access BR Monitor Assay – K033036
Device description:	The Access BR Monitor assay and the Access Immunoassay Analyzers comprise the Access Immunoassay Systems for the quantitative determination of CA 15-3 antigen levels in human serum and plasma.
Intended use:	The Access BR Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 15-3 antigen levels in human serum and plasma using the Access Immunoassay Systems.

Comparison of Technological Characteristics

Attribute	Access BR Monitor	Access BR Monitor (with modification)
Intended Use	For the quantitative determination of CA 15-3 antigen levels in human serum and plasma.	For the quantitative determination of CA 15-3 antigen levels in human serum and plasma.
Assay principles	The Access BR Monitor assay is a two-site immunoenzymatic ("sandwich") assay.	The Access BR Monitor assay is a two-site immunoenzymatic ("sandwich") assay.
Solid Support	Paramagnetic particles.	Paramagnetic particles.
Detection System	Chemiluminescent substrate.	Chemiluminescent substrate.
Calibrator	Six levels CA 15-3 antigen at levels of zero and approximately 10, 50, 100, 500, and 1000 U/mL in a buffered BSA matrix.	Six levels CA 15-3 antigen at levels of zero and approximately 10, 50, 100, 500, and 1000 U/mL in a buffered BSA matrix.
Analytical Range	0.5 – 1000 U/mL	0.5 – 1000 U/mL
Imprecision	This assay exhibits total imprecision of less than 10% across the assay range.	This assay exhibits total imprecision of ≤ 10% for concentrations between 15 and 500 U/mL, and ≤ 12% for concentrations greater than 500 U/mL.

Summary of Precision Study

Imprecision: Within-run assay imprecision was tested for concentrations from approximately 18 to 513 U/mL. The within-run imprecision ranged from 5.1 % CV to 9.6% CV. Between-run assay imprecision ranged from 3.1% CV to 5.8% CV. Total imprecision ranged from 7.7% CV to 10.8% CV.

Conclusion

Imprecision above 500 U/mL was the only performance characteristic revised in the Access BR Monitor assay and was not found to impact the safety and efficacy of the device. The modified Access® BR Monitor assay is substantially equivalent to the previously cleared Access® BR Monitor assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 26 2007

Beckman Coulter, Inc.
c/o Ms. Rachelle Parsons
Sr. Regulatory Specialist – RAC
1000 Lake Hazeltine Drive
Chaska, MN 55318

Re: k072612
Trade/Device Name: Access® BR Monitor and Access BR Monitor Calibrators on the Access Immunoassay Systems
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: MOI, JIT
Dated: September 14, 2007
Received: September 17, 2007

Dear Ms. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K072612

Device Name:
BR Monitor and BR Monitor Calibrators on the Access® Immunoassay Systems

Indication For Use:
The Access BR Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 15-3 antigen levels in human serum and plasma using the Access Immunoassay Systems. This device is indicated for use in the measurement of CA 15-3 antigen to aid in the management of breast cancer patients. Serial testing for patient CA 15-3 antigen concentrations should be used in conjunction with other clinical methods for monitoring breast cancer.

The Access BR Monitor Calibrators are intended to calibrate the Access BR Monitor assay for the quantitative determination of CA 15-3 antigen levels in human serum and plasma using the Access Immunoassay Systems.

Prescription Use ✓ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072612